510 (k) Summary
Eagle Eye® Gold IVUS Catheter / Avanar® F/X IVUS Catheter

K073473
Pg 1/3

Date Prepared: 7 December 2007
Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Arlene Blades
Manager, Regulatory Affairs

JAN 14 2008

Phone number: (916) 231-4558
Facsimile number: (916) 638-2647

Device Identification

- Device trade name: Eagle Eye® Gold IVUS Imaging Catheter and Avanar® F/X 2.9F IVUS Imaging Catheter
- Device common name: Cardiovascular Catheter

Classification Name:

	Class
➢ 870.1200 Catheter, Ultrasound, Intravascular	II
➢ 892.1570 Diagnostic Ultrasonic Transducer	II

Predicate Device:

The Eagle Eye® Gold Intravascular Ultrasound Imaging Catheter is substantially equivalent to the Eagle Eye® Gold IVUS Intravascular Ultrasound Imaging Catheter cleared under K051337 on August 18, 2005.

The Avanar® F/X IVUS 2.9F Intravascular Ultrasound Imaging Catheter is substantially equivalent to the Avanar® F/X 2.9F Intravascular Ultrasound Imaging Catheter cleared under K000820 on June 5, 2000.

Device Description:

The Eagle Eye® Gold and Avanar® F/X catheters incorporate a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The Eagle Eye® Gold and Avanar® F/X catheters utilize an internal lumen that allows the catheter to track over the 0.014" (0.36mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The Eagle Eye Gold catheter is introduced percutaneously or via surgical cut down into the vascular system.

The Eagle Eye® Gold and Avanar® F/X catheters may only be used with the Volcano s5 or Volcano s5i IVUS imaging systems and can also be used with Volcano VH IVUS system software v1.2 or higher. These catheters will not operate if connected to any other imaging system.

Intended Use:

The Eagle Eye® Gold catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Eagle Eye Gold ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

The Avanar® F/X 2.9F catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Avanar ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Device Technological Characteristics and Comparison to Predicate Device:
The Eagle Eye® Gold IVUS Imaging Catheter is substantially equivalent to: Eagle Eye™ Gold IVUS Imaging Catheter (Intravascular Ultrasound Imaging Catheter) cleared under K051337 on August 18, 2005. The Avanar F/X 2.9F IVUS Imaging Catheter (Ultrasound Intravascular Imaging Catheter) is substantially equivalent to: Avanar F/XIVUS Imaging Catheter cleared under K000820 on June 5, 2000. Modifications include changes to the material used for the Brachial and Femoral Marker Bands.

The fundamental scientific technology remains the same.

The Eagle Eye®Gold IVUS Catheter and the Avanar F/X® use the same fundamental scientific technologies and have the same *intended use as that of the predicate devices, Eagle Eye Gold (K051337) and Avanar F/X 2.9F (K000820).*

Performance Data:
Applicable testing was performed in accordance with the Design Verification Plan including a risk analysis addressing the impact of modifications to the device and components. The test results indicate the revised product is comparable to the predicate device. The new material was tested for biocompatibility according to ISO 10993-1 and the results met the predetermined acceptance criteria.

Conclusion:
The Eagle Eye® Gold IVUS Catheter and Avanar® F/X 2.9F IVUS catheters have the same *Intended Use* and utilize the same *fundamental scientific technology* as that of the predicate devices, *Eagle Eye Gold (K051337) and Avanar F/X 2.9F. (K000820).*

Modifications to the devices do not raise any new questions regarding safety or effectiveness. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the modified devices to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Volcano Therapeutics, Inc.
c/o Ms. Jennifer Motto
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K073473
Trade Name: Eagle Eye Gold IVUS Imaging Catheter, Model 85900,
Avanar IVUS Imaging Catheter, Model 85700
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter, Ultrasound, Intravascular
Regulatory Class: Class II (two)
Product Codes: OBJ, ITX
Date: December 6, 2007
Received: December 11, 2007

Dear Ms. Motto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073473

Device Name: Eagle Eye® Gold IVUS Imaging Catheter and Avanar® F/X 2.9F Intravascular Ultrasound Catheter

Indications for Use:

The Eagle Eye Gold catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Eagle Eye Gold ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

The Avanar F/X 2.9F Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Avanar catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number: OR K073473

Prescription Use X
(21 CFR 801.19)

Over-the-Counter Use _____